DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 28, 2015

Synthes USA Products, LLC
Ms. Susan Lewandowski
Project Leader, Regulatory Affairs - SMF
1302 Wrights Lane
West Chester, PA 19380

Re: K143285
Trade/Device Name: Mandible External Fixator – MR Conditional
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: April 28, 2015
Received: April 29, 2015

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K143285

Device Name
Mandible External Fixator - MR Conditional

Indications for Use (Describe)
The Mandible External Fixator is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facial fractures, burn maintenance, and bone grafting defects.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: April 28, 2015

Submitter: Synthes USA Products, LLC
1302 Wrights Lane East
West Chester, PA 19380
United States of America

Contact: Susan Lewandowski
Lewandowski.susan@synthes.com
Telephone: 610-719-5852
Facsimile: 484-356-9682

Device Name: Mandible External Fixator – MR Conditional

Device Classification Information:

Product Code	Device Name	Device Class	Regulation Number	Regulation Description
MQN	External Mandibular Fixator and/or Distractor	2	21 CFR 872.4760	Bone Plate

Predicate Devices:

- Synthes Mandible External Fixator (K040169)
- Synthes Mandible External Fixator (K050378)

Indications for Use:
The Mandible External Fixator is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facial fractures, burn maintenance, and bone grafting defects.

Device Description:
The Mandible External Fixator consists of the following components: Adjustable Parallel Pin Clamp; Adjustable Clamp; 2.5mm/4.0mm Schanz Screws; 2.0 mm K-wires; 2.5 mm K-wires;; 4.0 mm Pre-bent Titanium Rods; and 4.0 mm Carbon Fiber Rods. The rods and Schanz screws are available in various lengths.

Comparison to Predicate Devices:

Indications
The Mandible External Fixator has the same Indications for Use as the predicate devices.

Technological Similarities and Difference of Mandible External Fixator to the Predicates

- The predicate devices are the same as the devices included within this submission; components have not changed since their respective original clearances
- The difference between the subject devices and the predicate devices is the addition of MR Conditional scanning information to the labeling

Non-clinical performance data:
Non-clinical testing to support MR Conditional labeling include assessments of magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts.

The non-clinical performance data demonstrate that the Mandible External Fixator, when used in the MR environment using specified MR parameters and uses, is not adversely affected by magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts.

Clinical performance data:
Clinical testing was not necessary.

Substantial Equivalence:
The proposed devices have the same intended use as the predicate devices. The nonclinical testing included in this submission demonstrates that the Mandible External Fixator, when used in the MR environment using specified MR parameters and uses, is not adversely affected by magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts.

It is concluded that the information included in this submission supports substantial equivalence.